I. Claims 1-20, 41, and 42, drawn to a neural stem cell composition and a method of culturing neural stem cells, classified in class 435, subclass 368.

II. Claim 21, drawn to a method of preparing a genetically modified animal by introducing a neural stem cell into an oocyte, classified in class 800, subclass 21.

III. Claims 22-32, drawn to a cloned animal and a method of producing a cloned animal by nuclear transfer, classified in class 800, subclass 24.

IV. Claims 33-40, drawn to a cell culture medium, classified in class 435, subclass 325.

V. Claims 43 and 44, drawn to a method of treating a neurological disorder, classified in class 424, subclass 93.1.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents five separate and distinct inventions. The Examiner has further alleged that the inventions of Groups II-V are patentably distinct, because the "inventions are drawn to distinct and materially different methods". The Examiner specifically alleges that the "neural stem cell composition of the invention of Group I is structurally, chemically, biologically, and functionally distinct from the genetically modified animal of the invention of Group II, the cloned animal of the invention of Group III, and the cell medium of the invention of Group IV". The Examiner also admits that the cell culture medium of Group IV can be used in the method of Group I. The Examiner alleges, however, that the method of Group I is not limited to culturing neural stem cells.

The Examiner also alleges that the "inventions of Groups II and III-V are...drawn to materially different methods that require different starting materials, different modes of operation, and produce different effects." The Examiner also alleges that the "compositions of the inventions of Groups III-V are not required for and cannot be used in the method of the invention of Group II". The Examiner specifically alleges that the method of Group II "requires as starting materials a neural stem cell and an oocyte, whereas the method of...Group III requires a donor cell nucleus and an oocyte or

embryo." It is also alleged that the method of Group V involves treating a neurological disorder in a patient, whereas the method of Group II involves the production of a genetically modified animal.

The Examiner futher alleges that Groups III and IV-V are distinct because the cloned animal of Group III is structurally, biologically and functionally distinct from the cell culture medium of Group IV and the cloned animal of the invention of Group III is not required in the method of Group V.

Finally, the Examiner alleges that the cell culture medium of Group IV is not required for and cannot be used for carrying out the invention of Group V.

As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect to prosecute with traverse, the subject matter of Group III, Claims 22-32, drawn to a cloned animal and method of producing a cloned animal by nuclear transfer.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. §121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Group II, Claim 21 is

drawn to a method of introducing a neural stem cell into an oocyte or embryo to develop into a fetus or animal consistent with and in accordance with the claims of Group III. Notably, both Group II and Group III require the same starting materials, i.e. a cell and a nucleus derived from that cell. Moreover, the methods of Group III could not be performed without first obtaining a neural stem cell according to Group II. In addition, the methods of both Groups II and III are performed in a similar and related way, i.e. the stem cell or the nucleus are both introduced into the oocyte or embryo and the final effect is the same, namely a modified animal derived by using the neural stem cell or nucleus. Furthermore, the methods of Groups II and III produce a genetically modified animal.

In addition, the cell culture medium of Group IV is used to culture the composition of Group I. Moreover, the method of Group V employs the composition of Group I.

Accordingly, at least Groups II and III are very clearly interrelated and interdependent, not "independent and distinct". Applicants therefore submit that at least Claims 21-32 should be examined together in the present application.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicants' financial resources, a practice which arbitrarily imposes five-way restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the implementation of the General Agreement on Trade and Tariffs (GATT), Applicants are required either to conduct simultaneous prosecution, as here requiring excessive filing costs, or otherwise compromise the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicants' legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

The Examiner has justified the restriction requirement in this case by reference to the different subclasses of the Patent and Trademark Office classification system in which the five groups of claims would allegedly be classed. This basis fails to justify the restriction requirement in this application.

Reliance on the classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

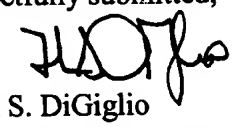
The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the subclass(es) with which the Examiner associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change,

thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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